APPLICATION

FOR

REISSUE OF U.S. PATENT NO. 5,462,157

TITLE: ELECTRODE PACKAGE

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ELECTRODE PACKAGE

BACKGROUND OF THE INVENTION

The invention relates to electrode packages.

Skin-applied electrodes used in medical applications such as cardiac pacing or defibrillation are well known. Typically, these electrodes consist of a wire lead that is attached at one end to a connector for a medical device and, at the other end, to a conductor such as a thin layer of tin or another metal resting on a foam backing. The conductor is covered with a water-based, conductive adhesive gel that contacts a patient's skin and electrically connects the electrode to the patient.

To prevent the adhesive gel from drying out, and to maintain the electrodes in a sanitary condition, the electrodes are stored in a package prior to use. In some such packages, plastic covers are positioned over the conductive adhesive gel of each electrode. The covered electrodes are then positioned within a sealed bag. To use the electrodes, medical personnel must tear open the bag, pull out and separate the electrodes, connect the electrodes to an appropriate medical device such as a defibrillator, remove the plastic covers, and apply the electrodes to the patient.

SUMMARY OF THE INVENTION

In one aspect, generally, the invention features an electrode package in which the conductive adhesive gel of an electrode is attached directly to an electrode mounting surface located on an interior surface of a wall of a releasably sealed envelope. When sealed, the envelope isolates the electrode from the external environment and thereby prevents the adhesive gel from drying out. To use the electrode, medical personnel tear open the envelope and expose the electrode.

Because the electrode is attached directly to the interior surface of the envelope, the steps of pulling the electrode out of the bag and removing the plastic cover that were required when using prior electrode packages are condensed into a single step of detaching the electrode from the interior surface of the package. The time saved by the elimination of a step can literally be the difference between life and death in an emergency situation. For example, when defibrillation is required, every second of delay in applying the electrode can be critical. Moreover, attaching the electrode to the interior of the envelope eliminates the risk of dropping the electrode that occurs when the electrode is loosely packaged within a bag or other container.

Typically, a second electrode is directly attached to an electrode mounting surface of a second interior surface of the envelope so that, when the envelope is sealed, the first and second interior surfaces face each other. The envelope is then unsealed in a manner similar to that of opening a book so that the two electrodes, like the facing pages of a book, are located on a single surface. This arrangement, which makes both electrodes readily accessible by medical personnel, further simplifies and accelerates the process of applying the electrodes to the patient. In addition, it provides a compact, efficient package.

For ease of assembly and use, the envelope is formed from a single sheet of material that is folded to form a first edge of the envelope and releasably heat sealed to form the remaining edges. This construction ensures that, when the envelope is opened, the electrode is fully exposed and readily available to medical personnel.

To further ease opening of the package, a pair of tabs are located opposite the folded edge of the envelope. To open the envelope, medical personnel need only grasp these tabs and pull them apart. This releases the heat seal and exposes the electrode.

The envelope also includes a reinforcing layer located at the electrode mounting surface. The reinforcing layer provides structural rigidity and protects the electrode.

Finally, to temporarily secure a wire lead of the electrode during assembly and to prevent the wire lead from becoming tangled, the envelope includes an adhesive strip located on its interior surface.

In another aspect, generally, the invention features an electrode package that has a first compartment in which an electrode is sealed, a second compartment in which a connector of the electrode is sealed, and a barrier element between the compartments that provides an electrically conductive path between the electrode and the connector. The barrier element allows the second compartment to be opened, and the connector exposed, without affecting the seal of the first compartment or exposing the electrode.

Because the connector can be exposed without exposing the electrode, the electrode can be preconnected to a medical device without the risk of contaminating the electrode or drying out its conductive adhesive layer. Thus, the electrode can be connected to the medical device before an emergency arises, and the step of connecting the electrode to the device, and its associated delay, can be eliminated from the electrode application procedure in an emergency situation such as when defibrillation is required.

The barrier element can also be employed in an electrode package having only a single compartment to similarly allow preconnection of the electrode to a medical device.

One method of implementing the barrier element includes forming a layer of material around a wire lead that is attached between the connector and the electrode. The layer is formed so that it includes an arcuate upper portion and an arcuate lower portion. To form the barrier element and seal the compartment, a first wall of the compartment is heat sealed to the arcuate upper portion, a second wall of the compartment is heat sealed to the arcuate lower portion, and the first and second walls are heat sealed to each other.

Another method of implementing the barrier element involves using the connector body as a portion of the barrier element. Typically, the body is formed from a single piece of material and includes an integral hinge. The body also includes strain relief posts that arranged so as to relieve strain on a wire lead located between the electrode and the connector. To ease formation of the barrier element and sealing of the compartment, the body includes a first end located in the compartment, a second end located outside of the compartment, and a central section that is used as part of the barrier element. The central section includes an arcuate upper portion and an arcuate lower portion and the barrier element is formed by heat sealing a first wall of the compartment to the arcuate upper portion, heat sealing a second wall of the compartment to the arcuate lower portion, and heat sealing the first and second walls to each other.

When the features of attaching electrodes to interior surfaces of the envelope and using an envelope having two compartments are combined, the process of applying the electrode to a patient is greatly simplified. Medical personnel no longer have to tear open a bag, pull out the electrodes, separate them, connect them to an appropriate medical device, remove plastic covers from them, and apply them to the patient. Instead, because the electrodes are preconnected

to the medical device, the medical personnel need only tear open the package, detach the electrodes from the package, and attach them to the patient.

Other features and advantages of the invention will be apparent from the following description of the preferred embodiments and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a top view of an electrode package in an unsealed configuration.

FIG. **2** is a top view of the electrode package of FIG. **1** in a sealed configuration.

FIG. **3** is a cutaway top view of a dual-compartment electrode package in a sealed configuration.

FIG. **4** is a cross-sectional view of the dual-compartment electrode package of FIG. **3**.

FIG. **5** is a cutaway top view of an electrode package in a sealed configuration.

FIG. **6** is a cross-sectional view of the electrode package of FIG. **5**.

FIG. **7** is a top view of an electrode connector in an open configuration.

FIG. **8** is a left side view of the electrode connector of FIG. **7**.

FIG. **9** is a right side view of the electrode connector of FIG. **7**.

FIG. **10** is a top view of a portion of the electrode connector of FIG. **7**, with wires inserted.

FIG. **11** is a front view of the electrode connector of FIG. **7** in a closed configuration.

FIG. **12** is a right side view of the electrode connector of FIG. **11**.

FIG. **13** is a cross sectional view of the electrode connector of FIG. **11**.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIG. **1**, an electrode package **10** (shown in an unsealed configuration) includes an outer sheet **12** on which is mounted a liner **14** that provides structural rigidity. Outer sheet **12** is made of a polyester, aluminum, TYVEK laminate. Liner **14** is made from styrene and is approximately two millimeters thick. Liner **14** is secured to outer sheet **12** by a pair of adhesive strips **15** that are implemented using double-sided adhesive tape attached between outer sheet **12** and liner **14**.

In use, electrodes **16**, **18** are attached to liner **14**. Wire leads **20**, **22**, which are attached at one end to a connector **24**, and at the other end, respectively, to terminals **26**, **28** on electrodes **16**, **18**, are temporarily secured by an adhesive strip **30**. Adhesive strip **30** is implemented using double-sided adhesive tape.

Referring also to FIG. **2**, which shows electrode package **10** in a sealed configuration, electrode package **10** is sealed by folding sheet **12** along an axis A so that electrodes **16**, **18** face each other. In this configuration, regions **32** contact regions **34**. Thereafter, regions **32**, **34** are heated to form heat seals **36**.

Tabs **40**, which are not sealed together, are used in opening electrode package **10**. Tabs **40**, focus, in a region **42** of heat seals **36**, a force applied to tabs **40** by, for example, an emergency medical technician pulling tabs **40** away from

each other. By focusing the force, tabs **40** minimize the force needed to break heat seals **36**. Once seals **36** are broken at region **42**, additional force on tabs **40** splits the remainder of heat seals **36** until electrode package **10** folds entirely open to expose electrodes **16**, **18** as shown in FIG. **1**.

Referring to FIG. **3**, a dual-compartment electrode package **50** includes an outer sheet **52** on which is mounted a liner **54**. As with electrode package **10**, electrodes **56**, **58** are attached to liner **54** and, when, as shown, dual-compartment electrode package **50** is sealed, face each other. Line **54** is attached to outer sheet **52** by a pair of adhesive strips **55**. As shown in the cutaway portion, electrode **58** attaches to liner **54** via a layer of adhesive gel **60** on electrode **58**.

Wire leads **62**, **64**, which are attached at one end to a connector **66**, and at the other end, respectively, to electrodes **56**, **58**, are temporarily secured by an adhesive strip **68**.

Referring also to FIG. **4**, sheet **52** is folded along an axis A so that regions **70** contact corresponding regions **72** from the opposite end of sheet **52** and are heated to form heat seals **74**. In addition, heat seals **76** are formed from regions **78** and corresponding regions from the opposite end of sheet **52**; heat seals **80** are formed between regions **82** and corresponding regions from the opposite end of sheet **52**; and heat seals **84** are formed between a gasket **88** and regions **86** of sheet **52**.

Gasket **88** is produced by forming a layer of RTV or a so-called "hot-melt" adhesive around wire leads **62**, **64**. Gasket **88** has an arcuate upper surface **90** and an arcuate lower surface **92**.

Gasket **88**, in combination with heat seals **76**, **80** and **84**, forms a barrier element between a first compartment **94** and a second compartment **96** of dual-compartment electrode package **50**. The barrier element allows second compartment **96** to be opened without opening first compartment **94**.

As shown in FIG. **4**, gasket **88** simultaneously maintains a seal between compartments **94**, **96** and allows wire leads **62**, **64** to pass between compartments **94**, **96**. Thus, gasket **88** provides an electrically conductive path between connector **66** and electrodes **56**, **58** even when electrodes **56**, **58** are sealed in compartment **94**.

As with electrode package **10**, dual-compartment electrode package **50** includes a pair of tabs **98** that are used in opening dual-compartment electrode package **50**.

Referring to FIG. **5**, an electrode package **100** includes an outer sheet **102** on which is mounted a liner **104**. Electrodes **106**, **108** are attached to liner **104** and, when, as shown, electrode package **100** is sealed, face each other. Liner **104** is attached to outer sheet **102** by a pair of adhesive strips **105**. As shown in the cutaway portion, electrode **108** attaches to liner **104** via a layer of adhesive gel **110** on electrode **108**.

Wire leads **112**, **114**, which are attached at one end to a connector **116**, and at the other end, respectively, to electrodes **106**, **108**, are temporarily secured by an adhesive strip **118**.

Referring also to FIG. **6**, sheet **102** is folded along an axis A and heated to form heat seals **120** between regions **122** from opposite ends of sheet **102**, heat seals **124** between regions **126** from opposite ends of sheet **102**, and heat seals **128** between connector **116** and regions **130** of sheet **102**.

Referring also to FIG. **13**, in a central region **134** between heat seals **128**, connector **116** has an arcuate upper surface **136** and an arcuate lower surface **138**. Connector **116**, in combination with heat seals **124** and **128**, forms a barrier element between a compartment **140** of electrode package

100 and the external environment. Connector 116 provides a seal for compartment 140 and an electrically conductive path between electrodes 106, 108 and terminals 142, 144, which are connected, respectively, to wire leads 112, 114.

Referring to FIGS. 7–13, connector 116, shown in an open configuration in FIGS. 7–9, includes a body 146 that is a single piece of molded plastic. Body 146 includes a base 148 in which terminals 142, 144 are positioned and a cover 150. Base 148 and cover 150 are connected by an integral hinge 152. Base 148 includes three pairs of strain relief posts 154, 156, 158, a pair of semicircular wire lead cutouts 160, and a pair of male locking tabs 161. Cover 150 includes a pair of semicircular wire lead cutouts 162, and a pair of female locking tabs 163.

At assembly, as shown in FIG. 10, wire leads 112, 114 are connected, respectively, to terminals 142, 144. Wire leads 112, 114 are then threaded around posts 154, between posts 156, and around posts 158 before passing through cutouts 160.

Once wire leads 112, 114 are in place, body 146 is folded along hinge 152 so that cover 150 is positioned on base 148 so that locking tabs 161 engage locking tabs 163. Cover 150 is then sealed to base 148.

Other embodiments are within the following claims. For example, connector 116 could replace gasket 88 in dual-compartment electrode package 50. Similarly, gasket 88 could replace connector 116 in electrode package 100. In addition, rather than mounting electrodes on the interior surfaces of dual-compartment electrode package 50 and electrode package 100, the electrodes could be loosely placed within the packages.